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EXAMINER

GABEL, G

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

12/02/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/268,437**

Applicant(s)

**Halsall et al.**

Examiner

**Gallene R. Gabel**

Group Art Unit

**1641**



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-9 is/are pending in the application

Of the above, claim(s) 6-9 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-5 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-9 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-5, drawn to simultaneous electrochemical assay device, classified in class 422, subclass 82.01.
  - II. Claims 6-7, drawn to method of testing and electrochemically detecting a plurality of analytes , classified in class 435, subclass 7.92.

Applicants are requested to note that a restriction requirement has been set forth for the following reason: while claims 1-5 appear to be drawn to a method, i.e. an electrochemical assay as set forth in the preamble of claim 1, all the claim limitations thereafter are drawn to elements in an electrochemical device or apparatus.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus may be used for clinical measurement of anaesthetic gasses based on amperometric electrochemical sensing.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination

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purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. Literature search for each method and apparatus is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

3. During a telephone conversation with Gregory Lunn on 11/16/99 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-5. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-9 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

#### ***Priority***

4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). Correction is required.

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*Abstract*

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the preamble as recited appears to be drawn to a method, i.e. an electrochemical assay, but the limitations are all drawn to an electrochemical device. See also claims 2-5.

Claim 1 is vague and indefinite in reciting "binding areas adapted to bind a different specific analyte" because it is unclear what is encompassed by the term "adapted" so as to render each of the binding areas specific to a different analytes.

The term "effective" in claim 1 is a relative term which renders the claim indefinite. The term "effective" is not specifically defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be

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reasonably apprised of the scope of the invention. By reciting “distance effective to permit a measurement by each electrode of analyte bound to its adjacent binding site”, applicants only provide a limited definition of the requisite degree of the term. For example, is there an acceptable range which separates the distance between each working electrode and adjacent binding area from the “nearest adjacent analyte binding area” allowable so as to prevent measurement of interfering amount of analyte in the nearest adjacent analyte binding area during analysis?

Claims 1-4 are indefinite and recite inconsistent language by reciting “binding area” and “binding site”. The claims appear to use the terms interchangeably or further fail to clearly recite them so as to be specifically differentiated.

Claim 5 is confusing in reciting “further comprising at least one auxiliary electrode” because it fails to specifically define the structural cooperative relationship between the at least one auxiliary electrode and each of the working electrodes adjacent to an analyte binding area. For example, is there at least one auxiliary electrode for every working electrode.

### ***Claim Rejections - 35 USC § 102***

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

7. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Meyerhoff et al. (US 5,981,203).

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Meyerhoff et al. disclose a simultaneous electrochemical multi-analyte immunoassay device. Meyerhoff et al. specifically disclose multiple metal electrodes coated on a same substrate (microporous membrane support) with each electrode having a binding site comprising analyte specific protein or antibody immobilized thereto for detecting the presence of electrochemically detectable analytes (see column 10, line 66 to column 11, line 5). The substrate serves as a solid phase for enzyme immunoassays and also as a support for the working electrode amperometric detection system (see column 5, lines 44-53). On the substrate, a layer of insulating material such as PVC, polyurethane, or polyethylene is cast completely around the electrode to improve precision and detection limits for the antibody assays by preventing portions of the conductive metal layer from exposure to reagent solutions on the diffusion layer adjacent to the electrode surface contributing to background signal from unbound antibody-conjugates in the bulk solution. Meyerhoff et al. further teach that by using a large area working electrode, one can minimize biological interferences present in the diffusion layer adjacent to the electrode surface (see column 6, line 47 to column 7, line 7). Both Figures 11 and 12 exemplify illustrations of the device for simultaneous dual analyte protein assays. In Figure 12, the simultaneous electrochemical device comprises the substrate mounted between diffusion chambers and coated with gold two metal discs which are gold working electrodes with antibodies immobilized thereto, i.e. anti-PSA and anti-hCG as capture antibodies, a common auxiliary platinum (counter) electrode and a common auxiliary Ag/AgCl (reference) electrode (see column 11, lines 6-42). Figure 15 shows a schematic representation of how simultaneous

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multiple protein electrochemical assay measurements can be carried out with a single substrate coated with array of working electrodes with various binding sites comprising different antibodies and also including auxiliary electrodes (see column 11, lines 50-55-8). Meyerhoff et al. teach that detection signals can be spatially distinguished so that assays using the device may be done with multiple enzyme-antibody conjugates labeled with the same enzyme, i.e. alkaline phosphatase.

8. For reasons aforementioned, no claims are allowed

***Remarks***

9. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Sluka et al. (US 5,851,840) disclose substrates made of polystyrene. Sluka et al. further disclose an analytical element for the determination of different analytes in a sample comprising a compartmented binding matrix in which a plurality of spatially separated or discrete zones are each covered with the same reaction partner or several layers of additional reaction partners wherein the binding can be detected by electrochemical means (see column 1, lines 29-31, column 9, lines 7-17, and column 11, lines 32-41)

Ducey et al. (Analytica Chimica Acta, 1997 (Abstract only)) teach a microporous gold electrode which serves as both working electrode and solid phase for the immobilization of binding protein/antibody through a chemisorbed layer of thioctic acid.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*G. Gabel 11/30/99*

Gail Gabel  
Patent Examiner  
Group 1641

*James C. Housel*  
JAMES C. HOUSEL 12/2/99  
SUPERVISORY PATENT EXAMINER